

DRAFT DOCUMENT

PESTICIDE REGISTRATION (PR) NOTICE 2002-XXXX

ATTENTION: Persons Responsible for Registration and Reregistration of Pesticide Products

SUBJECT: Compliance With Data Citation Regulations

I. INTRODUCTION

This Notice clarifies and emphasizes the existing obligations of applicants for FIFRA pesticide product registration who choose to cite other companies' data to satisfy EPA data requirements. In order for applications to satisfy the data submission and citation requirements for their products and to ensure that applications are processed properly, it is important that applicants who cite existing data make appropriate offers to pay compensation under FIFRA § 3(c)(1)(F). This PR Notice also reminds applicants and registrants to be especially aware of their obligations to those FIFRA task forces producing generic data (*i.e.*, data that are not specific to any active ingredient) on whose pesticide registration data they may rely.

II. SUMMARY

Applicants who choose to rely on data citation, rather than submitting their own data to meet EPA data requirements, must assure that the offer-to-pay letters they provide to data submitters satisfy EPA's regulatory requirements as provided in 40 CFR Part 152, Subpart E. When applicants do not follow these procedures, delays in the processing of registration applications result. In addition, improper offer-to-pay letters can increase the potential for adversarial petition actions brought under 40 C.F.R. § 152.99. When applicants do not comply

with data citation requirements, EPA, data submitters, and applicants expend, unnecessarily, significant resources during the application process. In an effort to avoid needless disputes and save the resources of all concerned, the Agency believes it would be helpful to clarify the obligations of data citers.

III. REQUIREMENTS FOR OFFER-TO-PAY-LETTERS

A. In General – Sending The Required Offer-To-Pay Letter

As described below, each applicant that claims to rely on previously-submitted data must provide data submitters with offer-to-pay letters when offering to pay compensation pursuant to FIFRA § 3(c)(1)(F) as required by regulation at 40 CFR Part 152, Subpart E. In addition, when applicants seek to satisfy outstanding data requirements, imposed on the applicant as a condition of registration, by cost sharing with existing registrants developing the data in response to an EPA data call-in under section 3(c)(2)(B), applicants should take special care to make clear in their offer-to-pay letters that they are offering to cost share (or jointly develop – or both) for such data as a means of satisfying a condition of registration.

B. Specific Regulatory Requirements For An Offer-To-Pay Letter

Applicants can satisfy Agency data requirements through one of two methods: (1) citing all relevant data in the Agency’s files (the “cite-all” method); or (2) demonstrating compliance with each applicable data requirement (the “selective” method). The following section will identify the steps applicants must follow when citing existing data utilizing one of these methods of data support.

1. Cite-All Application Method

EPA's regulations concerning applications under the cite-all method, 40 C.F.R. § 152.86, specify that, among other things, the applicant must certify to EPA that the applicant has made an offer-to-pay compensation to each person on the Data Submitters List for the chemical in question. This offer to pay must include:

1. Notice of his intent to apply for registration;
2. The name of the product;
3. A list of the product's active ingredients;
4. Offers to pay compensation to the extent required by section 3(c)(1)(F) for any data upon which the application relies and offers to commence negotiations concerning the amount and terms of compensation to be paid, if any; and
5. The applicant's name, address and telephone number.

Each applicant utilizing the cite-all method must satisfy each of these requirements. In addition, although not a regulatory requirement, the Agency encourages applicants to include a copy of the proposed label with their offer-to-pay letter(s). While the Agency understands that applicants may be reluctant to provide such information to a competitor, EPA believes that sharing information regarding proposed product uses can serve both to hasten and narrow the focus of discussions regarding compensation, thereby reducing the potential for submission to EPA of costly and time-consuming data compensation challenges.

2. Selective Method Applications

When applying for a registration action under the selective method, the requirements for the offer-to-pay letter are contained in the regulations at 40 C.F.R. §§ 152.90 and 152.95. The basic requirement of the offer-to-pay letter includes all five criteria set forth above for the cite-all method. In addition, under the selective method, each applicant must submit a detailed matrix listing each data requirement that applies to its pesticide product, its active ingredients, and its use patterns, as though the product were being proposed for registration for the first time pursuant to FIFRA § 3(c)(5). 40 C.F.R. § 152.90(a). It also must list each specific study that the application is citing to satisfy each data requirement if it is using a study specific citation method to meet one or more data requirements, or among other options, it may choose to “cite-all” data to satisfy a particular data requirement. As with the cite-all application method, an applicant can rely in its matrix on previously submitted studies, provided that its reliance is accompanied by appropriate offer-to-pay letters to owners of such studies as described above. In order for the data owner to evaluate the adequacy of the offer and commence negotiations, EPA encourages applicants to provide the data owner with a copy of the matrix showing the specific studies for which the applicant offers compensation to the data owner. As explained above with the cite-all method, the Agency also encourages applicants to include a copy of the proposed label with their offer-to-pay letter(s) in connection with applications utilizing the selective method of data support.

C. Satisfying Outstanding Data Requirements

In certain limited circumstances, applicants may defer satisfying EPA data requirements at the time of registration and will instead be required to satisfy the requirement upon a specified future date, as a condition of registration. For example, if EPA has issued to existing registrants a data call-in notice under section 3(c)(2)(B) of FIFRA to fill a gap in a pesticide's database, applicants for registration of products to which those data requirements apply must, as a condition of registration, satisfy the data requirement upon the time frames set forth in the data call-in notice for the existing registrants. Applicants for registration may satisfy these data requirements by either submitting the required data prior to or upon the required date, or by offering to cost share or jointly develop (or both) the data with an existing registrant (or a task force) that has committed to satisfy the data requirement. In addition to satisfying the requirements of section 3(c)(1)(F) regarding previously submitted data, offer to pay letters should also make clear whether the applicant is offering to jointly develop, or cost share for the development of data to satisfy any outstanding data call-ins. Accordingly, applicants should consider the deadlines for data submissions stated in DCIs and existing conditional registrations, and take note of those deadlines in determining the status of data responding to the requirements of an application for registration. The National Pesticide Information Retrieval Service (NPIRS), EPA Registration Eligibility Documents (REDs) and EPA's own Data Submitters List all provide information that can help an applicant to determine relevant task forces and the status of relevant data submissions.

IV. SPECIAL CONSIDERATIONS REGARDING TASK FORCES

As noted, EPA believes there may be a particular need to clarify obligations regarding the citation of data submitted by task forces. Industry participants have formed a number of pesticide registration task forces devoted to providing EPA with required data. Certain FIFRA task forces submit generic data pertinent to a large number of active ingredients and products rather than data generated specifically to support the registration of an individual ingredient or product. These task forces offer significant benefits to industry, EPA, and the public. Through the task forces, industry has generated the needed generic data more efficiently and economically, and brought together superior capabilities to produce high quality data. The task forces offer EPA significant benefits by focusing the Agency's resources for data review on many fewer data submissions. For the public, the task forces have assisted EPA in evaluating the safety of pesticide products and have helped maintain pesticide registrations by reducing costs. In the case of at least six task forces, industry is producing generic data that are required by EPA for a wide range of pesticide products. Since 1990, EPA has announced through PR Notices the formation of several task forces. PR Notice 90-3 announced the formation of the Spray Drift Task Force; PR Notice 94-9 announced the formation of both the Agricultural Reentry Task Force and the Outdoor Residential Exposure Task Force; and PR Notice 2000-2 announced the formation of the FIFRA Endangered Species Task Force. As any additional task force forms, the Agency anticipates issuing PR Notices to announce its formation.

Given the number of inquiries and complaints EPA has received from task forces, it is apparent that there may be a number of applicants who are not providing appropriate offer-to-pay letters to task forces in all cases where such letters are required. In many instances, task forces are now providing EPA with regularly updated lists of all parties who have joined or

provided offer-to-pay letters to each task force. These lists provide EPA with an opportunity to compare the task forces' records with an applicant's data citation forms to aid EPA's evaluation of the accuracy and completeness of the application. A large number of active ingredients and products must rely on data produced by these task forces to support their registrations. Each applicant for a registration action should be familiar with the data requirements to which task force data respond and should determine whether reliance on such data is required for the registration action it seeks.

V. NON-COMPLIANCE WITH OFFER-TO-PAY REQUIREMENTS

Incomplete and otherwise inadequate offers of compensation are a drain on Agency, data submitter, and applicant resources. Applicants who do not meet these requirements are in many instances likely to experience delays in approval of the registration actions they seek. EPA takes very seriously the legal obligation of pesticide applicants to provide offer-to-pay letters that do satisfy EPA's requirements. Ultimately, a failure to comply with these requirements can lead to denial of an application or cancellation of an existing registration, as set forth at 40 C.F.R. § 152.99.

VI. FOR FURTHER INFORMATION

Any questions regarding this PR Notice can be directed to Mark Dyner, Office of General Counsel, at (202) 564-1754 or Linda Arrington, Ombudsperson for the Registration Division, at (703) 305-5446.

Marcia E. Mulkey, Director

Office of Pesticide Programs